

PSJ3

Exhibit 674A



# Federation of State Medical Boards of the United States, Inc.

## Mission

Continual improvement in the quality, safety, and integrity of health care through the development and promotion of high standards for physician licensure and practice.

## Vision

Medical regulation will be performed through an interstate system of interconnected state boards structured as independent agencies with control over their resources, free of partisanship, federal control or special-interest influence, and utilizing consistent standards, language definitions and tools.

State medical boards will continue to be principal entities charged with maintaining and improving the quality of health care. As an interconnected system, state boards will share information and resources, work cooperatively, and avoid duplication of effort.

The Federation of State Medical Boards will be the national and international leader in the field of medical regulation and the authoritative source of research, policy analysis and development, education, and information. As a dynamic organization of state medical boards, the Federation will initiate and strengthen cooperation among boards, facilitate collaborative efforts between boards and other entities, develop unified policy positions and act as a trusted advocate for these positions.

## Core Values

**Public Protection and Accountability:** promoting the health, safety and welfare of the public through an interconnected system of independent state medical boards, accountable and responsive to the public.

**Leadership and Service:** demonstrating innovation, cooperation and responsiveness by dedicated individuals of high purpose and integrity.

**Excellence:** promoting and maintaining high standards of performance and a commitment to continuous improvement.

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## Goals

**Goal I.** With the leadership, assistance and support of the Federation, state medical boards will enhance their protection of the public and work to improve the quality of health care.

**Goal II.** The Federation will be the premier organization supporting and advocating for state medical boards, thereby achieving national and international recognition.

**Goal III.** The Federation's organizational structure and resources shall be adequate to achieve its vision and mission.

**Goal IV.** The Federation will anticipate trends in medical regulation, licensure and discipline and act to strengthen the role of state medical boards in a global health care environment.

**Goal V.** The Federation will lead, assist and support state medical boards in addressing changes in medical practice to assure and improve the quality of health care.

**Goal VI.** With the leadership, assistance and support of the Federation, state medical boards shall be independent agencies and

the primary vehicles of medical licensure and discipline.

**Goal VII.** With the leadership, assistance and support of the Federation, state medical boards will cooperate effectively, sharing both information and resources.

**Goal VIII.** With the leadership, assistance and support of the Federation, state medical boards will develop and use consistent standards, language, definitions and tools.



# Federation of State Medical Boards of the United States, Inc.

## FSMB Member State Medical and Osteopathic Boards

Alabama State Board of Medical  
Examiners  
Alaska State Medical Board  
Arizona Medical Board  
Arizona Board of Osteopathic  
Examiners in Medicine and Surgery  
Arkansas State Medical Board  
Medical Board of California  
Osteopathic Medical Board of  
California  
Colorado Board of Medical  
Examiners  
Commonwealth of Northern Mariana  
Islands Professional Licensing  
Board  
Connecticut Medical Examining  
Board  
Delaware Board of Medical Practice  
District of Columbia Board of  
Medicine  
Florida Board of Medicine  
Florida Board of Osteopathic  
Medicine  
Georgia Composite State Board of  
Medical Examiners  
Guam Board of Medical Examiners  
Hawaii Board of Medical Examiners  
Idaho State Board of Medicine  
Illinois Department of Professional  
Regulation  
Indiana Health Professions Bureau  
Iowa Board of Medical Examiners  
Kansas Board of Healing Arts  
Kentucky Board of Medical Licensure  
Louisiana State Board of Medical  
Examiners

Maine Board of Licensure in  
Medicine  
Maine Board of Osteopathic  
Licensure  
Maryland Board of Physicians  
Massachusetts Board of Registration  
in Medicine  
Michigan Board of Medicine  
Michigan Board of Osteopathic  
Medicine and Surgery  
Minnesota Board of Medical Practice  
Mississippi State Board of Medical  
Licensure  
Missouri State Board of Registration  
for the Healing Arts  
Montana Board of Medical Examiners  
Nebraska Board of Examiners of  
Medicine and Surgery  
Nevada State Board of Medical  
Examiners  
Nevada State Board of Osteopathic  
Medicine  
New Hampshire Board of Medicine  
New Jersey State Board of Medical  
Examiners  
New Mexico Board of Osteopathic  
Medical Examiners  
New Mexico Medical Board  
New York State Board for Medicine  
New York State Board for  
Professional Medical Conduct  
North Carolina Medical Board  
North Dakota State Board of Medical  
Examiners  
State Medical Board of Ohio  
Oklahoma Board of Osteopathic  
Examiners  
Oklahoma State Board of Medical  
Licensure and Supervision

Oregon Board of Medical  
Examiners  
Pennsylvania State Board of Medicine  
Pennsylvania State Board of  
Osteopathic Medicine  
Puerto Rico Board of Medical  
Examiners  
Rhode Island Board of Medical  
Licensure and Discipline  
South Carolina Dept. of LLR,  
Board of Medical Examiners  
South Dakota State Board of Medical  
and Osteopathic Examiners  
Tennessee Board of Medical  
Examiners  
Tennessee Board of Osteopathic  
Examiners  
Texas State Board of Medical  
Examiners  
Utah Osteopathic Physician and  
Surgeons Licensing Board  
Utah Physicians Licensing Board  
Vermont Board of Medical Practice  
Vermont Board of Osteopathic  
Physicians and Surgeons  
Virgin Islands Board of Medical  
Examiners  
Virginia Board of Medicine  
Washington Medical Quality  
Assurance Commission  
Washington Board of Osteopathic  
Medicine and Surgery  
West Virginia Board of Medicine  
West Virginia Board of Osteopathy  
Wisconsin Medical Examining Board  
Wyoming Board of Medicine



**Federation of State Medical Boards**  
***Promoting Balance and Consistency***  
***in the Regulatory Oversight of Pain Care***

**Agenda**

**April 7, 2005**

**Time**

- |                  |   |
|------------------|---|
| 1:00 – 2:00 p.m. | Registration – Pre-test   |
| 2:00 – 2:15 p.m. | <i>Welcome and Introductions</i><br>Lisa A. Robin<br>Vice President, Leadership and Legislative Services<br>Federation of State Medical Boards  |
| 2:15 – 3:30 p.m. | <i>Panel One: Pain</i><br>Moderator: Lisa A. Robin<br>Faculty: June L. Dahl, PhD; Scott Fishman, MD, Myra Christopher<br><ul style="list-style-type: none"><li>• Scope of Pain Management: Reflecting on the Past 20 Years</li><li>• War on Pain</li><li>• Ethics in Pain Care</li></ul>  |
| 3:30 – 3:40 p.m. | Break   |
| 3:40 – 4:40 p.m. | <i>Panel Two: Biological Basis of Chronic Pain and the Role of Opioid Therapy – Discussion, Question and Answer</i><br>Moderator: Lisa A. Robin<br>Faculty: Ed Covington, MD<br><ul style="list-style-type: none"><li>• Role of Opioids in Pain Management</li><li>• Acute and Chronic Pain</li><li>• FSMB Model for the Use of Controlled Substances for the Treatment of Pain</li></ul> |
| 4:40 – 4:50 p.m. | Break   |
| 4:50 – 6:10 p.m. | <i>Panel Three: Regulatory Responses to Abuse and Diversion – Discussion, Question and Answer</i><br>Moderator: June L. Dahl, PhD<br>Faculty: Bill Marcus, JD; Richard K. Markuson, RPh;<br>Michael S. Rodman; Michael A. Moné, JD, RPh<br><ul style="list-style-type: none"><li>• Strengths and Limitations</li><li>• Prescription Monitoring Programs</li></ul>                         |
| 6:15– 6:45 p.m.  | Reception for Attendees   |





**Federation of State Medical Boards**  
***Promoting Balance and Consistency***  
***in the Regulatory Oversight of Pain Care***

**Agenda**

**April 8, 2005**

**Board Member Track**

**Time**

7:30 – 8:00 a.m.	Continental Breakfast
8:00 – 9:45 a.m.	<p><i>Creating a Regulatory Environment Encouraging Appropriate Pain Care – Discussion, Question and Answer</i></p> <p>Moderator: June L. Dahl, PhD</p> <p>Faculty: Aaron Gilson, PhD; Michael A. Moné, JD, RPh; Patricia M. Good</p> <ul style="list-style-type: none"><li>• Pain Policy: Quest for Balance</li><li>• Pharmacy and Medical Boards Working Together to Create A Positive Regulatory Environment</li><li>• Best Practices: The Power of Joint Policy</li><li>• Federal Policy Update: Drug Enforcement Administration</li></ul>
9:45 – 10:05 a.m.	Break
10:05 – Noon	<p><i>Distinguishing Between Criminal vs. Incompetent/Negligent and Acceptable Practice – Including Discussion of Case Studies in Pain Management</i></p> <p>Moderator: June L. Dahl, PhD</p> <p>Faculty: Bill Marcus, JD; Ed Covington, MD</p>
Noon	Post-test, Evaluations, Announcements, Adjourn
12:15 p.m.	Lunch



**Federation of State Medical Boards**  
***Promoting Balance and Consistency***  
***in the Regulatory Oversight of Pain Care***

**Agenda**

**April 8, 2005**

**Board Investigator Track**

**Time**

7:30 – 8:00 a.m.	Continental Breakfast
8:00 – 9:30 a.m.	<i>What Are We Looking For?</i> Faculty: Arthur K. Thexton, JD Distinguishing between criminal negligent/incompetent behavior and failure to meet minimum standards of competence.
9:30 – 10:00 a.m.	<i>Working with Your Legal Team and Expert Witness</i> Faculty: Arthur K. Thexton, JD; Scott Fishman, MD Preparing the facts. Involving your expert witness.
10:00 – 10:15 a.m.	Break
10:15 – 11:15 a.m.	<i>Prescription Monitoring Programs</i> Faculty: Michael A. Moné, JD, RPh; Richard K. Markuson, RPh
11:15 a.m. – Noon	<i>Resources</i> Faculty: Robert Williamson Working with law enforcement and the DEA. Utilizing NADDI, the National Clearinghouse of Internet Prescribing, and other resources during the investigation process.
Noon	Evaluations, Announcements, Adjourn
12:15 p.m.	Lunch





**Federation of State Medical Boards**  
***Promoting Balance and Consistency***  
***in the Regulatory Oversight of Pain Care***  
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***General Information***

CME Information

Faculty Disclosure of Significant Relationships

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## Continuing Medical Education

**Course Director:** James N. Thompson, MD

**Accreditation:** This activity has been planned and implemented in accordance with the Essentials areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The University of Texas Southwestern Medical Center at Dallas and the Federation of State Medical Boards. UT Southwestern is accredited by the ACCME to provide continuing medical education for physicians.

**Credit Designation:** The University of Texas Southwestern Medical Center at Dallas designates this educational activity for a maximum of 8 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

**Disclosure:** It is the policy of ACCME that participants in CME activities should be made aware of any affiliation or financial interest that may affect the speaker's presentations. Each speaker has been requested to complete a Disclosure Form. The names of faculty members declaring potential conflict of interest or off-label discussion will be shown in the handout.

**Off-label Uses:** Because this course is meant to educate physicians with what is currently in use and what may be available in the future, there may be "off-label" or unapproved uses discussed in the presentations.

**Target Audience:** The *Promoting Balance and Consistency in the Regulatory Oversight of Pain Care* workshop is designed specifically for board members, which includes Family Physicians, and staff of state medical boards, as well as individuals concerned or interested in medical licensing, regulation and discipline.

**Method of Teaching:** Through presentations and discussions by distinguished faculty, the presenters will move attendees through the objectives stated.

**Educational Objectives:** At the end of the workshop, attendees should be able to:

- Create a regulatory environment that encourages accessible and appropriate pain care;
- Identify policy/legislative barriers to appropriate pain care;
- Describe abuse, diversion and the appropriate regulatory responses;
- Distinguish between criminal and negligent/incompetent and acceptable practice; and
- Define key terms and concepts related to pain and addiction.

**SOUTHWESTERN**

The University of Texas Southwestern Medical Center at Dallas, the accredited sponsor,  
is jointly sponsoring this activity with the Federation of State Medical Boards.

THE UNIVERSITY OF TEXAS  
SOUTHWESTERN MEDICAL CENTER  
AT DALLAS

Office of Continuing Education

**DISCLOSURE TO PARTICIPANTS**

NAME OF JOINT SPONSOR: Federation of State Medical Boards

NAME OF SERIES: Pain Management Workshop Series

NAME OF ACTIVITY: Promoting Balance and Consistency in the Regulatory Oversight of Pain Care

DATE OF ACTIVITY: April 7-8, 2005

COMMERCIAL SUPPORTER(S): None

According to ACCME's Standards for Commercial Support speakers involved in continuing medical education activities are required to disclose any real or apparent conflict(s) of interest related directly or indirectly to the activity as well as products not labeled for the use under discussion. This information is acknowledged solely for the information of the participant.

This symposium has been planned to be well-balanced and objective in discussion of comparative treatment regimens, and the symposium format allows for the free scientific exchange of ideas. Information and opinions offered by the speakers represent their viewpoints. Conclusions drawn by the audience should be derived from careful consideration of all available scientific information.

CONFLICT OF INTEREST DISCLOSURE

<u>Faculty</u>	<u>Affiliation</u>	<u>Organization</u>
Myra Christopher	Grant/Consultant	Aventis, Pfizer, Purdue Pharma LP
Ed Covington, MD	Consultant	Eli Lilly, Pfizer, Purdue Pharma LP
Scott Fishman, MD	Speaker/Consultant	Elan, Eli Lilly, Endo, Janssen, Merck, Pfizer, Purdue Pharma LP
Aaron Gilson, PhD	Grant /Consultant	Cephalon; Janssen; Purdue Pharma, American Cancer Society
Patricia M. Good	None	
Richard K. Markuson, RPh	None	
Bill Marcus, JD	None	
Michael A. Mone', JD, RPh	None	
Lisa A. Robin	None	
Michael S. Rodman	None	
Arthur Thexton, JD	None	
Robert Williamson	None	

OFF LABEL USE DISCLOSURE

Faculty: None

Product/Use: None

FAILED TO DISCLOSE

Faculty None





Federation of State Medical Boards  
*Promoting Balance and Consistency  
in the Regulatory Oversight of Pain Care*  
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Evaluation





# ***Pain***

Presented by:

**Lisa A. Robin**

Vice President, Leadership and Legislative Services  
Federation of State Medical Boards

**June L. Dahl, PhD**

Professor, Pharmacology  
University of Wisconsin Medical School  
Director, Wisconsin Cancer Pain Institute

**Scott Fishman, MD**

Chief, Division of Pain Medicine  
University of California, Davis

**Myra Christopher**

President and Chief Executive Officer  
Midwest Bioethics Center





***Promoting Balance and Consistency  
in the Regulatory Oversight of Pain  
Care***

**Lisa A. Robin**

**Vice President, Leadership and Legislative Services  
Federation of State Medical Boards**



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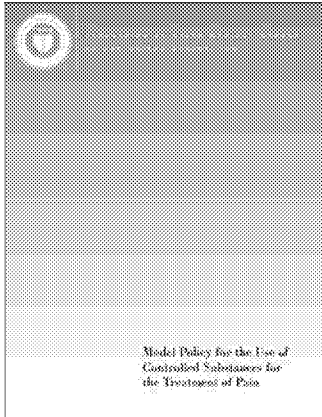
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Pain & Policy Studies Group

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**Purpose of the Model Policy**

- Encourage pain management, more consistent policy
- Encourage appropriate use of opioids
- Address fear of regulatory scrutiny
- Criteria for evaluating physicians care
- Deviation from policy for cause-flexibility
- Under treatment is below standard of care
- Safeguard against abuse and diversion
- Evaluate and address regulatory barriers

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**The Model Policy Is Not:**

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- **To constrain, or regulate medical decisions**
- **To be used as clinical practice guidelines**
- **Inconsistent with Controlled Substance laws and regulations**

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**Promoting Balance and  
Consistency in the Regulatory  
Oversight of Pain Care**

**Federation of State Medical Boards  
Boston, Massachusetts  
April 7-8, 2005**

June L. Dahl, PhD  
University of Wisconsin Medical School  
jldahl@wisc.edu

Dahl 2005

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**Pain**

- A common human malady that spares no group and often impairs function
- Occurs in a variety of forms – acute due to injury; chronic due to episodic conditions such as migraine or to chronic persistent problems such as arthritis

Dahl 2005

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**Pain**

- The most common reason persons seek medical attention
- Can serve as a warning sign to tell us that something is wrong in our bodies
- But if it is not controlled, it has significant adverse physiological and psychological consequences
- And there is much evidence that pain is often not adequately controlled

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**The undertreatment of pain  
has been identified as a  
major public health problem  
in the United States**

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**Pain of all kinds is  
inadequately treated**

- Post-op, trauma and procedural pain
- Cancer pain
- Chronic non-cancer pain:  
furthermore, clinicians often  
question the validity of the pain  
report in these patients

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**Acute Postoperative Pain**

- More than 25 million surgeries each year
- More than half of post-op patients have  
unrelieved pain
- Pain may lead to shallow breathing and cough  
suppression and delay the return of gastric and  
bowel function
- Pain delays healing
- Unrelieved acute pain is a risk factor for the  
development of chronic pain conditions

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## **Cancer Pain**

- >500,000 deaths each year
- 70% of patients have pain as a major symptom
- 80-90% of pain is easily controllable
- >50% of persons with pain receive inadequate treatment

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## **Persistent Non-cancer Pain**

- >100 million persons with chronic pain
- 50 million are partially or totally disabled for various periods
- For most, pain is the primary factor that prevents a productive life
- What is the cost?

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## **Data from the American Productivity Audit**

- Captures a large, representative national sample of the US workforce
- Assesses lost productive time due to health conditions, with a specific focus on common pain conditions
- Survey respondents report 1) time absent and 2) reduced performance while at work due to pain overall and due to specific pain conditions

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## American Productivity Audit

- Estimated pain-related lost productive time and the associated costs due to headache, back pain, arthritis, and other musculoskeletal problems
- Lost productive time from common pain conditions among active workers costs an estimated \$61.2 billion per year.
- The majority (76.6%) of the lost productive times was explained by reduced performance while at work and not work absence. JAMA 2003; 290: 2443-2454

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## Dr. Dennis Turk: Nov 5, 2004

- President of the American Pain Society
- US Bureau of the Census, 1996
- Annual total cost of health care, disability & related expenditures due to chronic pain: estimated to be \$150 billion

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## Why do we have such a problem?

Why aren't we doing a better job of managing pain?

- 150-200 years ago physicians viewed pain as a sign of a patient's vitality
- Surgeons felt that pain was critical to healing
- We now know that pain is much more than an unpleasant sensation
- Pain should be prevented and treated
- Why is there such a gap between what we know and what we do?

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## **Barriers to Effective Pain Management**

- Health care professionals
- Patients, families and the public
- The health care system
- The drug regulatory system
- The reimbursement system

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## **Health Care Professionals**

- May receive little training in pain assessment and treatment
- May lack knowledge of pain physiology and pharmacology
- May not consider pain management a priority; few rewards for effective pain control; inadequate reimbursement for time
- May have excessive concerns about opioid side effects, especially about tolerance and dependence

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## **Patient/Public Barriers**

- Low expectations for relief
- Fear of reporting pain
- Desire to be “good” patients
- Fear of the drug side effects
- Fear of tolerance and addiction
- “Won’t I get dependent?”

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## Barriers in the System

- Pain has had low priority
- No accountability for poor pain management
- Lack of practical treatment protocols
- Fragmentation of care
- Lack of coordination of care

These barriers are addressed in pain standards from the Joint Commission so accredited facilities can no longer ignore pain. Pain is now being assessed. Has there been an impact on pain care?

Documented disparity in care based on gender, race and ethnicity

- "Isn't it amazing how much pain we can tolerate in other persons?"

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## What about barriers in laws and regulations?

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## Improving Palliative Care for Cancer Institute of Medicine National Research Council

**Reform drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering.**

National Academy Press, Washington, DC, 2000. Page 41

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## Drug Regulations

- Nothing in federal law prevents appropriate use of opioids for pain control
- However, states have promulgated regulations which may have a chilling effect
- The War on Drugs has made the public and professionals fearful of opioids
- Opiophobia was prevalent even before the abuse of Oxycontin

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## The good news: more attention is being paid to pain

- In the last 20 years, a variety of factors have led physicians to rethink their approach to pain
  - ✓WHO analgesic ladder
  - ✓Various pain guidelines
  - ✓Patient advocacy groups
  - ✓New drugs, new delivery systems
  - ✓JCAHO standards

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## Opioid Prescribing has Increased: 1997-2002\*

- |                 |      |
|-----------------|------|
| • Morphine      | 73%  |
| • Hydromorphone | 98%  |
| • Fentanyl      | 227% |
| • Oxycodone     | 403% |
| • Meperidine    | -6%  |

\*ARCOS

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### Has the pendulum swung too far?

- No question that opioids are the drugs of choice for moderate to severe pain associated with surgery or trauma and for pain due to cancer
- However, clinicians are at times confused about the role of opioids for the treatment of chronic (persistent) pain not related to cancer

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### Medical Use and Abuse

- Media reports suggest legitimate prescribing and medical use is a major contributor to opioid abuse and addiction.
- Are there data to support that conclusion?

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### What is the risk of addiction?

The use of narcotics in the terminal cancer pain is to be condemned. Morphine usage is an unpleasant experience to the majority of human subjects because of undesirable side effects. Dominant in the list of these unfortunate effects is addiction.

Lee LE Jr. Medications in the control of pain in terminal cancer, with reference to the study of newer synthetic analgesics. JAMA 1941; 116-217.

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### **“Potent opioids for chronic musculoskeletal pain: flying blind?”**

Pain 2004; 109: 207-209

The authors commented on a report that the use of potent opioids for musculoskeletal pain increased from 2% in 1980 to 9% in 2000

They concluded that these “dramatic changes in prescribing patterns raise significant concerns”

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### **Continued Concerns**

- “Epidemic” of Oxycontin abuse
- Reports of harassment of physicians by licensing boards and by law enforcement
- Clinician questioning of opioid use: is it safe to prescribe these drugs long term? Is there a maximum safe dose for chronic use?

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### **Resurgence of Fears**

- Reports of aggressive actions by the DEA have increased physician paranoia
- The DEA’s interim policy statement published in November in the Federal Register has dramatically increased physicians’ fears and confusion

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## The Challenge

- Bring rational thought to the dialog
- Bring balance and consistency to regulatory oversight
- Bring balance and consistency to the community of health care professionals who treat pain with opioids

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## Never forget the impact on patients

Pain is like a symphony conducted by the brain with major input from various instruments within the body and mind sections. The sounds can be as varied as those from an orchestra, and too often it's hard to know exactly which instruments are playing, particularly when sweet healthy melodies turn into blaring nightmarish noises.

Scott Fishman, The War on Pain 2000

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Medical Boards are committed to protecting the public and improving the quality and integrity of health care. Never forget the impact that regulatory actions may have on patients in pain

A critical question from a 33-year old Wisconsin woman with injuries to her cervical spine who was denied treatment with opioids because of physician fears about the appropriateness and legality of such treatment:

**“Why is it that this unwelcome visitor has become a permanent resident with very bad manners?”**

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## The War on Pain

# The War on Pain

**Scott M. Fishman, MD**  
 Professor and Chief  
 Division of Pain Medicine  
 Department of Anesthesiology  
 and Pain Medicine  
 Univ. of California, Davis  
 School of Medicine

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## Compulsory Opening Joke Physician Humor

- Includes brief story telling
  - » Often complex scenario
  - » May be improbable circumstances
  - » Must highlight special role of physician
    - ~ Inadequacy
    - ~ Embarrassing behavior
    - ~ Over valued by mother
      - or mother surrogate
  - » May include nurses
    - Hippocrates, prior to managed care

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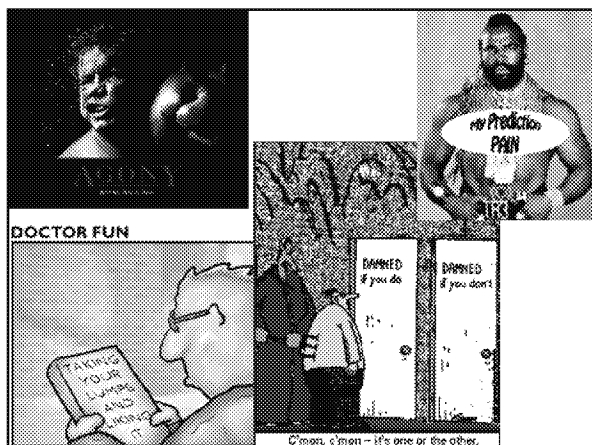
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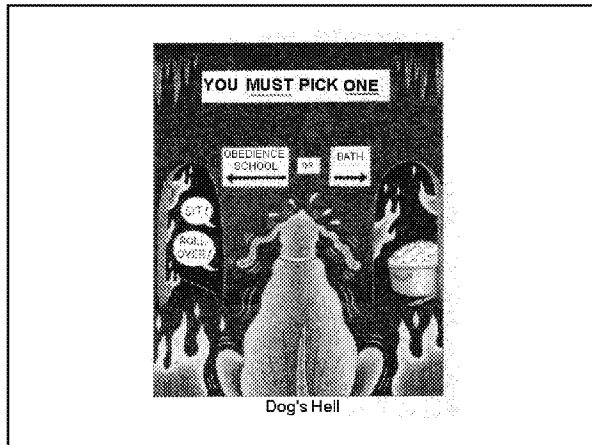
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**New Laws:  
Damned if we Do or Don't**

- **Over Prescribing Opioids**
  - » Reckless malpractice
  - » Manslaughter or Murder
  - » Federal Charges for Drug Traffic
- **Under Treating Pain**
  - » Elder Abuse

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"I can't touch my shoulders with my hand" he says. "I have popped elbows. My knees don't straighten out anymore! That's what you get from wrestling! I have knots on my spine and a big hollow on my neck. That's not right-- That's abnormal. I used to go into the ring with a separated shoulder -- now one is lower than the other. My whole body's a wreck! But am I in pain? Nooo! I don't accept pain."



**Or zap the pain.**

Immediate pain relief without drugs.

And the next morning the "Zap" became the "The New York Times," the world's most powerful newspaper, the paper that defined the world. It was the first time that the world had been defined by a single newspaper.

[illegible]

The Simulator 879

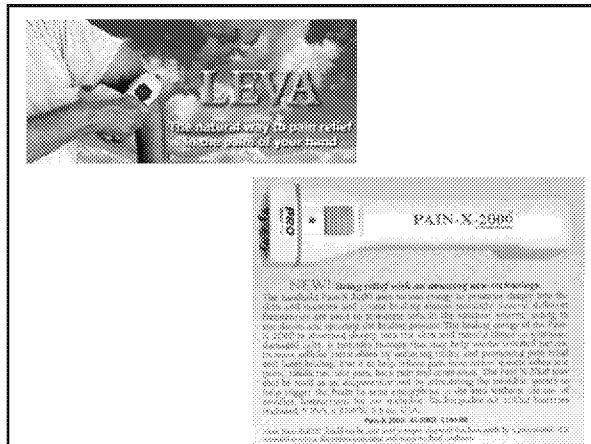
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• *ACUPUNCTURE ZAPPER*



Experience the helpful effects of acupuncture without the needles! When used correctly, **The Magna-pulse Zapper** offers temporary relief from many of the aches and pains experienced by outdoor enthusiasts without drugs or harmful side effects. **The Zapper** comes with a handy carrying case, a special adapter for hard to reach spots and a 137 page book detailing the proper use of **The Zapper** with instructions and diagrams illustrating the acupuncture points and how to use them. **The Magna-pulse Zapper** is available from **The Natural Health Marketplace** for only \$69.95 + \$6.00 shipping and handling. This is the exact same electronic stimulator that is currently being advertised for \$10 and \$20 more. Plus the other electronic stimulators do not come with a carrying case and a 137 page instruction booklet. Call now,  **toll-free 1-800-871-0900** to order your powerful **Zapper** for only \$69.95, that's 1-800-871-0900 to experience the benefits of acupuncture without needles!

**Warning:** Do not use *The Sinner* if you are pregnant or if you have a nose ulcer.




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**IT WORKS!**

All Natural Pain Relief

Safe, Fast, and Effective

*Easy twist-off top*

\$12.00 plus \$3.00 shipping and handling per jar.

Money Back Guarantee



**RAINFORCE WONDER GEL**

*Pain Relieving Gel*



*With ingredients from the Rain Forest*

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**PAIN PATCH**



**Natural, Non-Invasive Pain Relief**

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# !! Super Blue Stuff

for Lower Back & Sciatic Nerve Pain

You have nothing to  
lose except for your  
**PAIN!**

- Jack McQuinn

## Super Blue Stuff™

The New Revolutionary Solution for Your Pain!

Now, Not Just Used... You can't avoid this one!

**Super Blue Stuff™**  
Fast Relief Gel

\$895.00 - 125

**Save 50%**

plus \$6.99 shipping and handling  
within 48 hrs of purchase

Buy now and get  
your instant  
**Super Blue Stuff™**  
set ready shipped.

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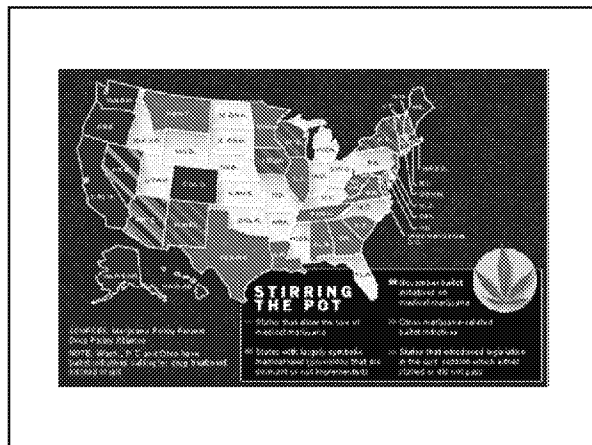
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### Medical Marijuana

- 2001 Supreme Court ruled, in an 8-to-0 decision in *United States v. Oakland Cannabis Buyers' Cooperative*
  - » CSA does not allow an exception for medical purposes to its prohibitions on the manufacture and distribution of marijuana

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### Medical Marijuana

- 2002 Ninth Circuit Court of Appeals in San Francisco, in a 3-to-0 decision in *Conant v. Walters*
  - » Physicians have a constitutionally protected right to discuss the medical use of marijuana with their patients and to recommend it
  - » \*\*\* Cautioned physicians against aiding their patients in obtaining marijuana
- AG appeals to Supreme Court
- 2003, Supreme Court declined to hear appeal
  - » leaving previous decision intact

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### Latest Legal Challenge to Medical Marijuana

- In October 2002, Monson and Raich sued the attorney general and the administrator of the DEA
- In May 2004, Federal district court issued a preliminary injunction
  - » Protecting the two women
  - » Protecting their supplies of medical marijuana

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### Latest Legal Challenge to Medical Marijuana

- 2004 June - Supreme Court agrees to hear Ashcroft's appeal via *Raich v. Ashcroft*
  - » ? What is the extent of the federal government's authority over medical marijuana use
  - » ? Does CSA apply to all marijuana use
  - » ? Does AG have authority in all situations:
    - ~ "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California law"

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### Statistics on Chronic Pain

- 44 million (43 %) American households
  - » At least one family member who suffers from chronic pain due to a specific illness or medical condition (Foley, Partners Against Pain, Purdue Pharma)
  - » Costs Americans more than \$100 billion each year in health care costs and lost productivity (National Institute of Health)

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### Statistics on Chronic Pain

**"80% of surveyed pain sufferers believe that pain is an unavoidable part of their medical condition and something they must live with."**

(Foley, Partners Against Pain, Purdue Pharma)

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## So Where Do We Really Stand on Treating Pain

- Most everyone is for it
- Conflicting messages
  - » Law
  - » Public
- Undertreatment & Overtreatment
  - » Neither are well tolerated
  - » No addiction
  - » No PAS
- Doctors may feel Damned if they do or don't

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## Where Do We Stand Children in Pain

- Am Academy of Pediatrics
  - » *There is ample knowledge about pain to treat children humanely and effectively – but it is not universally applied*
  - ~Myth: Children don't feel pain
    - Especially infants
  - ~Myth: Pain builds character in children
  - ~Lack of assessment of pain in children
  - ~Unreasonable fear about side effects

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## Where Do We Stand The Elderly in Pain

- Nationwide study on pain in 2.2 million residents of US nursing homes
  - » 14.7% were in persistent pain
  - » 41.2% of residents who reported pain
    - ~ were in severe pain 60 to 180 days later
  - » Data reported by nursing home staff rather than by patients
    - ~ Results underestimate the true pain experienced by nursing home residents

- Center for Gerontology and Health Care Research at Brown Univ. Medical School
- Teno JM, Weitzen S, Welle T, Mor V. Persistent Pain in Nursing Home Residents. [Research Letter]. *JAMA*. 2001;285(16):2081

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### Where Do We Stand Gender Differences

- Women in pain
  - » More likely than men to seek treatment
  - » Less likely to receive it
    - ~ Hoffmann DE, Tarzian AJ. *J Law Med Ethics*. 2001; 29:13-27
  - » *"Women are at greater risk for inadequate pain relief and continued suffering"*

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### Where Do We Stand Gender Differences

- Gender-based bias against pain in women
  - » Myths:
    - ~ Women can handle more pain
    - ~ Women imagine pain where none exists
- Based on these presumptions
  - » Health care providers may not actually listen to women's complaints

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### Where Do We Stand Minorities in Pain

- *Untreated Pain is a Public Health Crisis for Minorities*
  - » National Medical Association (NMA) Panel
- Study from MD Anderson Cancer Center
  - » Socio-economically disadvantaged African Americans and Hispanics are not adequately treated for pain
    - ~ Especially women
    - ~ Approximately ½ as likely to get adequate Tx
    - ~ Anderson, et al: *Cancer* 2002; 94: 8, pp. 2295-2304

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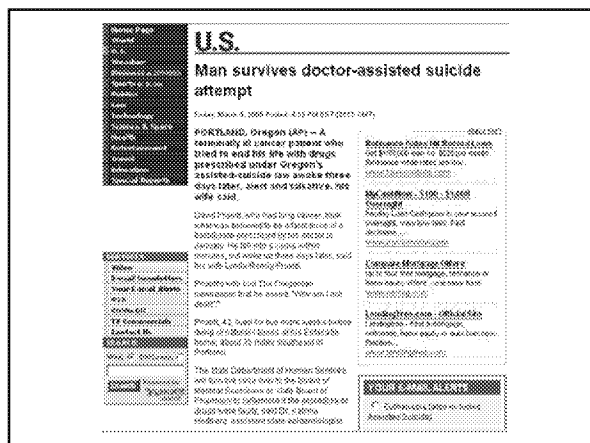
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# Where Do We Stand

## Patients with Cancer

- The National Cancer Institute
  - » 8.4 million Americans with a history of cancer
  - » 1.2 million new cases this year
- Pain in Cancer
  - » 1/3 patients undergoing active treatment
  - » 70 percent ++ with advanced disease
  - » Fewer than half receive adequate pain relief
- Children with cancer
  - » 89% suffered substantial pain
    - ~ which could have been treated more effectively



## So Why is Tx Pain So Hard

"An unpleasant sensory and emotional experience arising from the actual or potential tissue damage or described in terms of such damage. Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life.... It is unquestionably in a part or parts of the body, but it is also always unpleasant and therefore an emotional experience"

*– International Assoc. for the Study of Pain*

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## PAIN

- Untestable Hypothesis
- Many Meanings
  - No two patients the same
- It's All in Your head
  - Mind always modulates pain
  - Its usually also in the body
- Mind & Body
  - Inextricably Linked

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## Managing Pain

- 1 . Will to Treat
  - » Appreciating the need
- 2 . Acceptance of Risks
  - » Balanced Position
    - ~ The barriers to Tx
    - ~ The consequences of Tx
      - Addiction
      - Hastening Death
    - ~ The consequences of taking no action
      - Suffering
- 3 . Treatments

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## PAIN

- When There is Pain
  - » There is no risk free option

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## Barriers to Effective Pain Management

- Healthcare professionals
- Patients and family members
- Healthcare and regulatory systems

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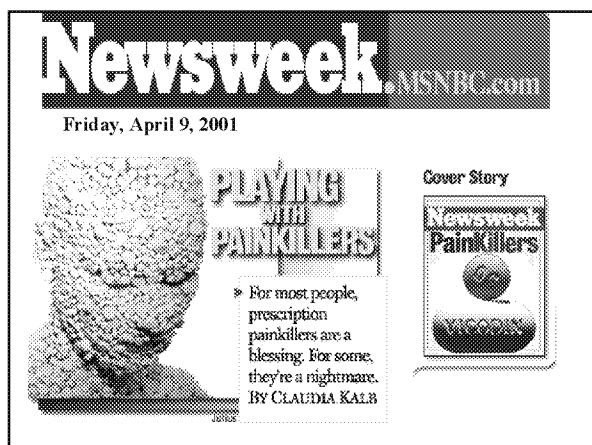
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## Addiction Cost to Society

### • \$245.7 billion for 1992

» *Estimate of the total economic cost of alcohol and drug abuse*

» *The Lewin Group*

~ *National Institute on Drug Abuse (NIDA)*

~ *National Institute on Alcohol Abuse and Alcoholism (NIH)*

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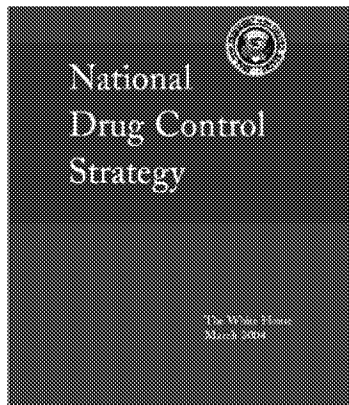
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## OxyContin Addiction Help

1-800-942-2056

Free Legal Consultation  
Contact Us Here

Users addicted  
as a result of  
OxyContin



Free Legal Consultation Drug Courts Fact Sheet Addiction & Abuse Drug Courts U.S.S. 1/14/2004

OxyContin, marketed by Purdue Pharma L.P., has been linked to addiction, suffering and death of patients using this prescription painkiller. Addiction and abuse of the drug, crime and fatal overdoses have all been reported as a result of OxyContin use.

OxyContin, approved by the FDA in 1995, is a time-released form of oxycodone, an opium derivative, which is the same active ingredient in Percodan and Percocet. OxyContin is intended for use by terminal cancer patients and chronic pain sufferers. It has been linked to at least 120 overseas deaths nationwide.

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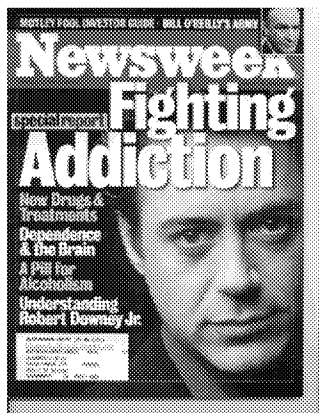
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## Celebrities Suffering from Addiction

Newsweek April 9, 2001

By Cindy McCain- Wife of Senator John McCain

**How a senator's wife, suffering from back pain and embroiled in a scandal, got addicted to painkillers and kept it a secret**

*Even My Husband Never Knew.— It began with Vicodin.*



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## Addiction in the Media

- 11 pm Local News
  - » “Oxycontin – Pain Killer or People Killer?”
- 20/20 Monday, 20/20 Tuesday, 20/20 Wednesday, PrimeTime, Dateline, Nightline, 60 Minutes
  - » Side 1:
    - ~ Dr. Feelgood hauled out of his practice for creating addicts
  - » Side 2:
    - ~ Dr. Healgood unjustly hauled out of his practice by evil protectors of addiction

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## Addiction in the Media

- **PROTOTYPE**

- » **ER**

- ~ ER Resident stabbed in back by crazed schizophrenic
      - Kills Med Student
    - ~ Resident gets chronic LBP
    - ~ Resident Takes Vicoden
    - ~ Resident soon steals fentanyl from patient
      - Witnessed injecting himself in ER

- » **Moral of Story**

- ~ Got Pain – Get Pain killers – Get Addicted
      - & your Doctors are probably Addicted Too

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## Terms Associated with Opioid Use

- **Addiction**
  - » psychological component
  - » drug-seeking behaviors
  - » nonmedical use of drug despite potential harm
- **Pseudo-addiction**
  - » iatrogenic problem - inadequate analgesia
- **Tolerance**
  - » rare in cancer patients
  - » not relevant to efficacy if agents and dosage are adjusted
- **Physical Dependence**
  - » natural process; weaning from drug is a simple medical process

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## Dependence vs. Addiction vs. Abuse

- **Clonidine**
- **Cocaine**
  - Gambling, Food, Sex
- **Entrepreneurs**

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## Addiction vs. Pain Patients

- Patients with addiction take increasing amounts of abusable drugs
  - » Function does not improve
    - ~ Usually worsens
- Patients usually find a stable dose
  - » pain doesn't completely abate
    - ~ balance of least pain/most function
  - » Function improves
    - » DOES NOT DECREASE
      - » If decrease → does NOT = Addiction

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## Correlation of Pain Intensity and Impact

### Activities Impaired by Increasing Pain Severity

					Relate
				Walk	Walk
			Sleep	Sleep	Sleep
		Active	Active	Active	Active
		Mood	Mood	Mood	Mood
	Work	Work	Work	Work	Work
Enjoy	Enjoy	Enjoy	Enjoy	Enjoy	Enjoy
3	4	5	6	7	8
>>>>>>>	>>>>>>>	>> Worst Pain Rating >>	>>>>>>>	>>>>>>>	>>>>>>>

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Cleeland CS, Ryan KM. *Ann Acad Med Singapore*. 1994;23:129-138.

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## Pharmaco-Vigilance with Opioids

- Requires understanding of functional outcomes
  - » Side effect management
    - ~ Improved function → Efficacy
    - ~ Static or decreased function → ? Efficacy ? Toxicity
- Universal Precautions
  - » Standardized programs that apply to all
    - ~ Consistent risk management practices
    - ~ Persistent vigilance
    - ~ Minimized bias

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**Federation of State Medical Boards  
of the United States, Inc.**

***Model Policy for the Use of Controlled  
Substances for the Treatment of Pain***

FSMB House of Delegates  
May 2004  
Available [www.fsmb.org](http://www.fsmb.org)

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***FSMB Model Policy***  
*Basic Tenants*

- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief
- Use of opioids for other than a legitimate medical purpose poses a threat to the individual and society

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***FSMB Model Policy***

- Physicians have a responsibility to minimize the potential for abuse and diversion
- Physicians may deviate from the recommended treatment steps based on good cause
- Not meant to constrain or dictate medical decision-making

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### ***FSMB Model Policy***

- Complete patient evaluation
- Written treatment plan
- Informed patient consent and agreement for treatment
- Periodic review of the course of treatment
- Willingness to refer
- Maintenance of complete and current medical record

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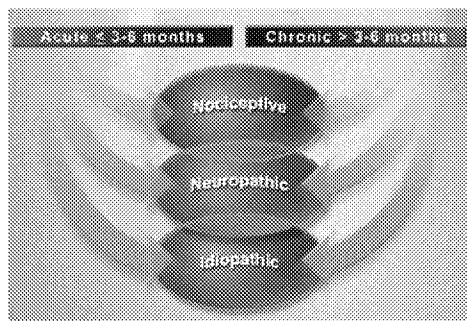
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### **Types of Pain**




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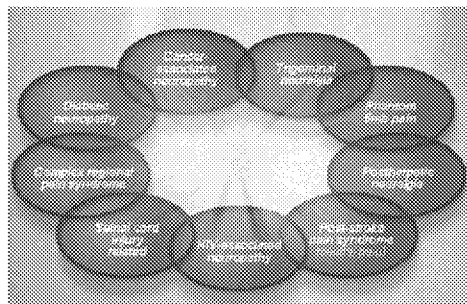
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### **Spectrum of Neuropathic Pain**




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## Neuropathic Analgesics

- Membrane Stabilizers
  - » Anticonvulsants
  - » Antiarrhythmics
  - » Local Anesthetics
- Opioid Stabilizers
  - » NMDA blockers
- Others

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## Drug Therapies for Pain

- Weak analgesics
- Strong analgesics
- Neuropathic analgesics
- Analgesic adjuvants
- Routes of Administration
 

• Oral	• Nasal
• Transdermal	• Intravenous / PCA or subcutaneous
• Transmucosal	• Intrathecal or epidural
• Rectal	• Intraventricular
	• Iontophoresis

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## Common Adjuvant Analgesics

### Opioid Sparing Agents

Drug Class	Most Common Use
NSAIDs	Bone metastasis, soft tissue infiltration, serositis, arthritis
Corticosteroids	Soft tissue infiltration, acute nerve and/or spinal cord compression, visceral distention, increased intracranial pressure, bone metastasis
Tricyclic Antidepressants	Neuropathic pain
Anticonvulsants	Neuropathic pain
Neuroleptics, Benzodiazepines, Stimulants	

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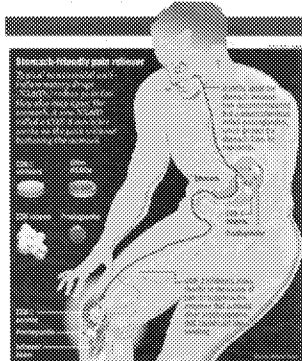
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## NSAIDs

COX-1  
COX-2  
COX-3?




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## COX-2-Specific Inhibitors

Generic Name	Brand Name	Approval Year
Celecoxib	Celebrex®	1998
Rofecoxib	Vioxx®	1999-2004
Valdecoxib	Bextra®	2001
Paracoxib	??	??

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## OPIOID ANALGESICS



- The Gold Standard
  - » Severe Pain
  - » Unremitting Pain




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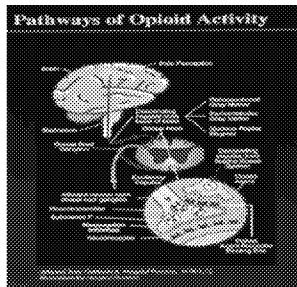
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## Endogenous Opioids

- The body's internal morphine
  - » Endorphins
  - » Enkephalins
  - » Dynorphins



## Methadone

- Analgesic vs Plasma half life are different
  - » onset: 15 min
  - » peak effects 60-120 minutes
  - » analgesic half life: 4-6 hours
  - » plasma half life: 21-24 hours
- Oral
  - » 5-10mg bid - qid ??
- Parenteral

## Methadone

- Equianalgesic Dosing
  - » Opioid Naïve
  - » Opioid Tolerant
- Unstable Biometabolism

## Treatment Targets of Analgesia

- Persistent Pain
  - TX: Long Acting Analgesics
- Breakthrough Pain
  - TX: Rapid Onset Short Acting Analgesics
    - Incident
    - Idiopathic/spontaneous
    - End-of-dose failure

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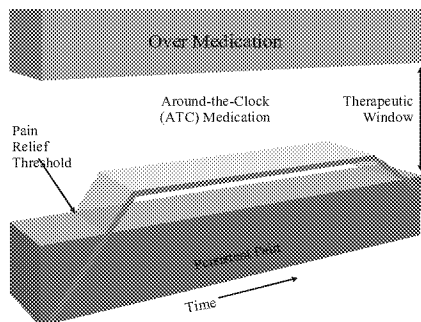
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## Treating Persistent Pain—Theory




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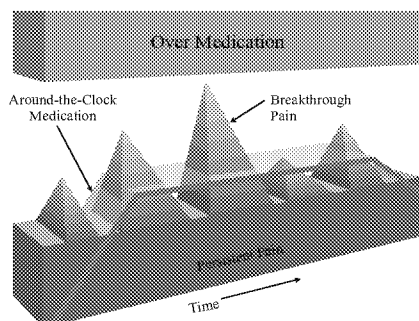
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## ATC Medications—Shortcomings




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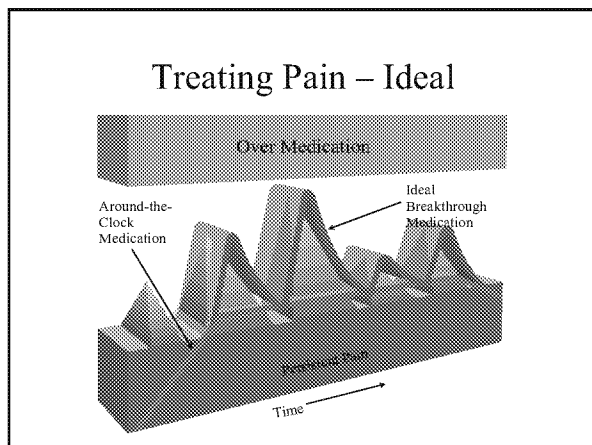
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- ### Interventional Treatments for Pain
- **Injection Therapies**
    - » Epidural space: LA, Steroid, Clonidine, etc
    - » Nerves: nerve roots, peripheral n., sympathetic n.
    - » Joints: Facet, SI, etc
    - » Muscles: Piriformis (Botox)
  - **Implantable Therapies**
    - » IT Pumps (opioids, LA, clonidine)
    - » Spinal Cord Stimulators

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- ### Nonpharmacological Pain Treatment
- **Physical Rehabilitation**
    - ~PM&R component
    - ~Functional Restoration
  - **Psychological Rehabilitation**
    - ~Cognitive Behavioral Psychology
    - ~Biofeedback, Hypnosis, relaxation
    - ~Group Therapy

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## SUFFERING

- Overlap of Pain Medicine & Psychiatry
  - Subjectivity with few objective markers
  - Common comorbidity
  - Common pharmacopia

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## Analgesia / Psychopharmacology



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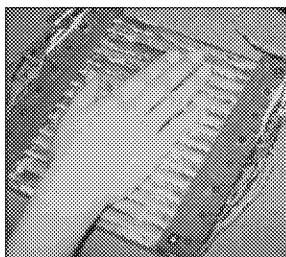
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## The Thermal Grill Illusion

Craig AD and Bushnell MC: Science 265, 1994



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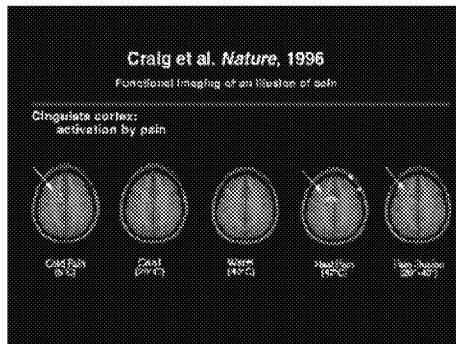
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## The Thermal Grill Illusion




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## The Mind-Body Connection

- How do Some Tolerate So Much Pain
  - » People Do Extraordinary Things
    - ~ Man Lifts Car Off His Leg
    - ~ Walking on Hot Coals
  - » Elite Athletes
    - ~ Marathon Runners
    - ~ Iron Man Competitors
    - ~ Injured Athletes

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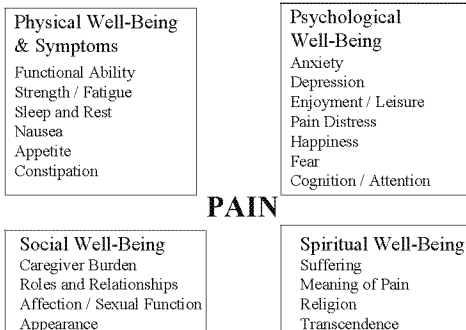
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## TREATING SUFFERING: Improving Quality of Life




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*QUESTIONS?*



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## On the Road to Reform: Advocacy and Activism in End-of-Life Care

ERIKA BLACKSHER, M.A. and MYRA CHRISTOPHER, B.S.

### ABSTRACT

This paper argues that the general public is, and should be, an important source of activity in end-of-life care reform. Two roles for the public are described: personal advocacy and public activism. The first relates to the role of private citizens in advocating on their own or a loved one's behalf at the end of life to secure quality palliative care. The second relates to the role of leaders in mobilizing reform efforts on behalf of the larger society. These roles overlap and often function to bolster one another. Numerous examples of how advocacy often transforms into activism and how activism relies on advocacy are given, drawn from the experience of directing Community-State Partnerships to Improve End-of-Life Care, a national program housed at Midwest Bioethics Center in Kansas City, Missouri.

### INTRODUCTION

**P**ROBLEMS WITH END-OF-LIFE CARE in the United States have been well documented and much discussed.<sup>a</sup> Even before clinical investigators began researching and documenting the failures of American medicine and its health care systems to deliver good palliative care, bioethicists were debating the moral dimensions and features of a "good death." Together, these lines of inquiry, discussion, and research have produced a good degree of consensus among health care professionals, bioethicists, and others as to the basic constituents of good end-of-life care.<sup>b</sup> Although physician-assisted suicide still gives rise to heated debate, many observers agree that what

this country needs is ambitious social reform to ensure the delivery and reimbursement of good end-of-life care.<sup>c</sup>

Calls to action point not only to the roles of health care professionals, payers, and policy-makers but to the public. Everyone agrees that cultural change cannot happen without the public, and past examples of publicly led reforms aimed at U.S. health care are often cited as proof (e.g., the natural birthing movement or care of persons with human immunodeficiency virus/acquired immune deficiency syndrome [HIV/AIDS]). Yet, everyone also agrees that the issue of death and dying presents unique and serious barriers to the public's willingness to take action. Indeed, some have concluded that the current

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Community-State Partnerships to Improve End-of-Life Care, Midwest Bioethics Center, Kansas City, Missouri.

<sup>a</sup>For example, SUPPORT Principal Investigators: A controlled trial to improve care for seriously ill hospitalized patients. *JAMA* 1995;274:1591-1598; and Field MJ, Cassel CK eds: Committee on Care at the End of Life, Division of Health Care Services, Institute of Medicine. *Approaching Death: Improving Care at the End of Life*, Washington, D.C.: National Academy Press, 1997.

<sup>b</sup>For example, Cassel CK, Foley KM. Principles of Care of Patients at the End of Life: An Emerging Consensus among the Specialties of Medicine. Milbank Memorial Fund, 1999; The Precepts of Palliative Care, Last Acts Task Force on Palliative Care, 1997.

<sup>c</sup>See, for example, John Arras, Physician-Assisted Suicide: A Tragic View, in *Frontiers in Bioethics*, ed. Franklin G. Miller, University Publishing Group, 2000, pp. 57-81.

end-of-life care movement is largely void of this powerful force for change.<sup>1</sup> We disagree.

In this paper we press two points about the public's role in end-of-life care reform. The first is qualitative in nature and addresses the many linkages between personal experience and public action. The second is quantitative in nature and addresses our sense of the degree to which the public is interested and involved in end-of-life care reform. We do not maintain that the public is active to the extent that it needs to be; much work remains. But we do believe the public can be found in all corners of this movement: leading it, moving it, waking up to it. Our task here is primarily descriptive, and we will draw largely on our 4-year experience as directors of a national program funded by the Robert Wood Johnson Foundation, Community-State Partnerships to Improve End-of-Life Care.

### FROM PRIVATE TO PUBLIC AND BACK AGAIN

Two important roles for the public are commonly identified in end-of-life care reform: personal advocacy and public activism. Personal advocacy refers to action taken by an individual to ensure that good care is received by a particular person, often oneself, a family member, or loved ones. Advocacy requires motivated consumers capable of learning about advance care planning, pain and symptom management, spiritual care, and reimbursement policies; and effectively demanding the best of these on behalf of themselves or their loved ones. Activity at this level draws on private resources and experiences. Public activism, however, refers to activity organized and undertaken by a collective on behalf of a collective—a group of patients with the same disease or condition, hospitalized patients, nursing home residents, or a community, state, or the society at large. The targets of reform here are policies and practices that influence the care that all people receive. Public citizens may be directly involved in this activity, although more often they are represented by organizations. Activity at this level draws on the resources and power of public organizations and representatives.

Advocacy and activism often overlap. Evidence that the private experience of those who care for dying persons has shaped this country's

end-of-life care movement is abundant. These experiences—good or bad—leave an indelible impression that eventually becomes active. It has been suggested that being a caregiver for a dying person is so all consuming and stressful that these private advocates are disabled from becoming public activists—especially during the caregiving experience. However, once these people have grieved and recovered, they are often the very people who become motivated to take public action. Katrinka Smith-Sloan, director of life resources for the American Association of Retired Persons (AARP), has observed this phenomenon in working on the AARP's Family Empowerment Initiative, a project that helps family members of long-term care residents understand and navigate long-term care facilities. "What we saw clearly was that people who had had an experience with long-term care—whether positive or negative—had a lot to say and often got involved" (personal conversation, July 19, 2001).

Indeed, end-of-life care leaders rarely lack a personal and profound story. Whether working on clinical or policy reform, or at the local or national level, reformers are often driven by firsthand experience. Numerous examples can be given. Take Ira Byock, director of a Robert Wood Johnson Foundation national program to improve end-of-life care, cofounder and principal investigator at the Missoula Demonstration Project in Montana, past president of American Academy of Hospice and Palliative Medicine, and author of *Dying Well: Peace and Possibilities at the End of Life*. *Dying Well*, which begins with the story of his father's dying. According to Byock, although he had initiated a "hospice-like" program in the teaching hospital where he was a resident over a year before his father showed signs of having a terminal diagnosis, his interest in "dying well" did not come into focus until his father's illness and eventual death.<sup>2</sup> When he initiated the hospital program to better coordinate care for terminally ill patients, he had no "special insight into dying," says Byock, "nor did I have any special interest in terminal care." But once his father died, things changed: *he changed*. "After my father's illness I began to question my assumptions about dying and everything I had been taught about the care of the dying."<sup>3</sup>

Chuck Butler, vice president of government and public relations of Blue Cross Blue Shield in Montana, was, similar to Byock, compelled to



initiate policy reform after experiencing his mother's death. His mother had openly expressed her wishes to die peacefully, but she had surgery only days before she died. Because her husband was unprepared for and unwilling to accept her death, he insisted that the physicians "do another surgery." Butler says this experience forever changed him and motivated him to endorse and support the creation of an advanced illness program that facilitates the coordination and continuity of care, providing both patients and their families with the services they need to prepare for dying and death. "I only hope that through my work on this program I can help some other family, so they don't have to go through what my mother, my sisters, and my father and I did" (personal conversation, July 25, 2001).

The road to activism is not always this straight. Cindy Keeney, vice president of clinical services for the Kentucky Hospital Association and project director of Journey's End, a statewide coalition to improve end-of-life care, describes her first encounter with a patient named Louise as "paralyzing." One year out of nursing school, Keeney found herself caring for a frail elderly woman with terminal lung cancer. They had developed a rapport, so much so that Keeney would sign up to care for Louise on her days off. But her care for Louise turned, in Keeney's words, "hellish," when she was forced to hold her frail friend down while she was intubated. "Louise locked her blue eyes on me and would not turn away. She was furious with me. She wanted nothing more to do with me" (personal conversation, July 25, 2001). This experience did not move Keeney to work toward improved care of terminally ill patients; rather, she refused to care for cancer patients—until, that is, her husband was diagnosed with non-Hodgkin's lymphoma 6 years later. Keeney, by now a well-established health care professional, had to fight to get the kind of care her husband wanted. "All eight of my husband's physicians agreed Bill had absolutely no hope of survival; yet it took days to get a no-code order" (personal conversation, July 25, 2001). She did eventually get a do-not-resuscitate order, then much to her and others' surprise, her husband began, very slowly, to recover. Keeney interpreted this unlikely turn of events in religious terms. "When I began to hope that my husband would survive, I felt a tremendous amount of responsibility. I thought, 'If I am going to dare hope he

will survive, I am going to have to make it worthwhile for God,'" says Keeney (personal conversation, July 25, 2001). She and her husband became activists together and since the late 1990s have worked on insurance coverage, advance directive issues, and hospital visitation policies.

Similar stories can also lead to activism aimed at physician-assisted suicide. Many commentators have noted that the public's support for physician-assisted suicide has been motivated by people's legitimate fears of dying in pain and "tethered to technology." Because we do not endorse physician-assisted suicide as good or wise public policy, we view this activism as unfortunate, even if understandable. Yet, surprisingly, physician-assisted suicide activism has helped raise awareness about dying and aided efforts to improve end-of-life care. The experiences of Maine and Oregon are illustrative here. Both states have faced referenda on physician-assisted suicide. The former rejected the measure and the latter passed it, but reformers in both states claim that physician-assisted suicide activism, although difficult to endure, ultimately aided their cause.

The citizens of Maine voted on a referendum on physician-assisted suicide in November 2000. Long-time reformer Kandyce Powell, executive director of the Maine Hospice Council and project director of the Maine Consortium for Palliative Care and Hospice, said the referendum forced the issue of death and dying before the citizens and policymakers of Maine, fueling a discussion and debate that took place in the media, town hall meetings, and anywhere Mainers gathered. For those working to improve the care of dying persons, it was both a painful experience and an unprecedented communications opportunity. "End-of-life care was discussed as it never had been before," Powell said (personal conversation, July 12, 2001). This awareness seemed to incite a new level of commitment to the issue. "For some, when the campaign was over, so was their 'concern' about improving end-of-life care in Maine. For others (including the legislature), the referendum created an increased sense of responsibility" (personal conversation, July 12, 2001). In June 2001, the Maine legislature passed the End-of-Life Care Statute, which promotes access to quality end-of-life care by extending the 6-month diagnosis limit for terminal illnesses to 12 months, mandating hospice coverage for all covered lives, increasing reimbursement rates for



hospice care, and creating a state center dedicated to end-of-life care reform, among other measures.

Reformers in Oregon saw a similar response when Ballot Measure 16, The Oregon Death with Dignity Act, passed with 51% of the voters. Susan Tolle, professor of medicine and director of the Center for Ethics in Health Care at Oregon Health Sciences Center, has argued that "the election spurred a new willingness among professional organizations and healthcare systems to improve care of the dying."<sup>4</sup> Not long after the election, Oregon hospitals developed and funded palliative care teams; hospice referrals increased, and a more extensive curriculum for medical students and practicing professionals was developed and implemented. "Suddenly, this place had discovered palliative care," Tolle said. A study by Linda Ganzini and colleagues,<sup>5</sup> conducted in 1999 to examine physician attitudes and practices regarding care of dying persons, corroborates Tolle's observation. Ganzini and colleagues found that 30% of respondents reported that they had increased referrals to hospice and that 76% of respondents had made efforts to improve their knowledge of and use of pain medications in terminally ill patients.

These anecdotes and examples illustrate some of the serendipitous and surprising ways the experience of private individuals is converted into fuel for public activism. But the end-of-life care movement also benefits from intentional efforts to integrate citizens' experiences and views into policy and practice reforms. Often referred to as "public engagement" or "civic engagement," the process involves convening ordinary citizens to study, share, and discuss experiences of and problems with end-of-life care. "[Public engagement] asks citizens to participate in their community—to frame the problems facing them in their own way—and seek cooperative solutions."<sup>6</sup>

Four goals are commonly identified for public engagement. They are to gather information, educate individuals, build community, and reform policy. Collecting the stories and views of ordinary citizens and mining these views for underpinning values helps reformers move in the right direction and provides a basis for improving standards, practices, and policies. An important example of public engagement came from a 1997 national study of Americans sponsored by American Health Decisions, a nonprofit organization

that helps people understand health care choices, express the values that inform them, and participate in personal health care decisions and public policy development. The study, "The Quest to Die with Dignity," found that Americans shared similar concerns, values, and attitudes about the process of dying, which suggested several practice and policy reforms. Prior to and after that study, a number of similar efforts were carried out by health decisions groups around the country working at the community and state level. Examples include the work done by Sacramento Healthcare Decisions and the Georgia Health Decisions group, among others.

Statewide coalitions and partnerships that received grants from the Community-State Partnerships to Improve End-of-Life Care program, have been convening citizens since 1999, when many of these projects got underway.<sup>7</sup> Tribal meetings, rotary clubs, church groups, town hall meetings, and a number of other settings have served as venues for public discussion, education, and storytelling. The coalitions have used these opportunities to accomplish several goals. They have gathered information regarding the viewpoints and barriers to good end-of-life care, which they then used to inform their respective statewide plans of action. They have also educated citizens and provided them with tools to help them plan and advocate for themselves and their loved ones at the end of life. And they have used all these opportunities to motivate citizens and their communities to become informed and involved. The Hawaii coalition, Kokua Mau, for example, reached between 4,000 and 5,000 Hawaiians in 1999 and 2000 through their speakers' bureau, a mechanism for public outreach that most Community-State Partners have created.

Beyond its utility, public engagement may also yield intrinsic goods, such as opportunities to heal or to attach larger meaning to one's personal loss. A number of Community-State Partnership coalitions have observed that people, although initially hesitant, appreciate the opportunity to talk about these issues. In Utah, where the Part-

<sup>4</sup>Community-State Partnership grantees are in 21 states: Alabama, California, Connecticut, District of Columbia, Florida, Hawaii, Iowa, Kansas, Kentucky, Maine, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, North Carolina, North Dakota, Oklahoma, Rhode Island, Utah, and West Virginia.

nership to Improve End-of-Life Care used a program created by Jay Jacobson and colleagues at LDS Hospital in Salt Lake City, Utah, called "Dialogue to Action," focus groups with more than two dozen family members have been conducted in the past 2 years to share their stories of recently deceased loved ones.<sup>7</sup> Chris Bennett, a nurse ethicist and faculty member in the medical ethics division of LDS Hospital and the University of Utah School of Medicine, reports that people do not understand the program initially. "People will initially say, 'I don't need that,' or 'It will be too difficult for me,'" Bennett said. But when they understand the purpose of the program and attend the groups, they always express deep gratitude for the opportunity to talk about the experience and to be really listened to. They also want their experience to help others by making end-of-life care better. "People feel incredibly better after talking about it," Bennett said, "and they tell us to keep holding the dialogue groups." Jennifer Fowler, project coordinator of Journey's End, the Kentucky end-of-life care coalition, agrees. "People need to heal and these discussion groups function to help them to do just that," she says.

## THE GROUND IS SWELLING

Thus far we have described some of the ways in which private citizens have become integral to end-of-life care reform as well as some of the goods that result from such involvement. But is it fair to say that "the public" is on board the end-of-life care movement? The answer will likely depend on how one defines "the public" and what one expects them to do. We think it is fair to say that the public is definitely "getting on board." To support our optimistic outlook we look not only to popular culture, but also to reforms initiated by the health care and public policy bodies that serve and are accountable to the public.

### *Popular culture*

From high culture to low culture, death and dying have been on the minds of Americans. Plays, films, television series, books, and cartoons

have recently featured the topic of death, and it appears that the public is watching and reading. The Pulitzer Prize winning play *Wit*, which chronicles a professor's experience of advanced ovarian cancer, was a much-publicized hit on Broadway. Since its New York debut, the play has been performed in more than 100 professional and amateur theaters in every state in the union.<sup>8</sup> The play has also been made into an HBO movie, which is scheduled for rebroadcast. The play had such a lasting effect on audiences that a *Wit* educational initiative has been created and funded to bring *Wit* readings or full performances to medical students, medical residents, and faculty. The initiative is funded to take *Wit* into 30 medical schools, but the initiative's program director, Jillisa Steckart, says that they have received at least 20 to 30 additional requests and more are expected. "We could not have imagined the blossoming of this initiative," Steckart says. "We are preparing to expand it. Our goal is to make this a regular part of palliative care curriculum in every medical school" (personal conversation, August 7, 2001).

*On Our Own Terms*, Bill Moyers's four-part PBS series, had a similar effect on the American public. Seventeen million viewers watched the premiere of the series, followed by another 3 million viewers who watched the program during subsequent months when it was rebroadcast. The series was rated among the top 10 most-watched PBS programs of the year and beat the average PBS prime-time audience numbers by 58%. A community outreach effort launched to complement the series fostered the formation of over 300 community coalitions throughout the United States, all of which hosted events and discussion groups on end-of-life care. Debbie Rubenstein, executive director of special projects for Public Affairs Television said, "The project as a whole is considered to have been the most successful public television outreach for the year and, by many measures, ever. It has been an integral element of the renewed conversation within PBS about its mission to serve the community" (personal conversation, August 6, 2001). The number of viewers is expected to reach 30 million when the series is offered for rebroadcast in fall 2001 in conjunction with the a national newspaper series, "Finding Our Way: Living with Death in America," supported by Knight Ridder Tribune. To top the accolades, the series was featured on the cover

<sup>7</sup>This number reflects nonprofessional theaters and a smattering of professional theaters; the actual number may be much larger.

of *Time* magazine, a magazine written to track the public's interests.

The public's chord was struck again by Mitch Albom's *Tuesdays with Morrie*, the story of weekly visits with his mentor Morrie Schwartz. In dying as in life, Morrie was a kind and wise professor. The book, which has been on the *New York Times* bestseller list for 197 weeks, became a television movie in December 1999.

We could mention a long list of additional examples, some more pedestrian, including television programs such as *Ally McBeal* and *Seinfeld* or cartoons such as *Doonesbury* and *Family Circus*. That end-of-life issues have been featured in media that must appeal to the public's interests and sensibilities to survive, attests to the public's receptivity and willingness to watch, read, cry, and even laugh at stories of our dying.

### *Clinical capacity*

Another measure of the public's concern with these issues is reflected in the reform activities initiated by professional associations and other bodies that shape the treatment that health care consumers receive, demand, and expect. At every level—national, regional, state, community—groups accountable to and responsible for the training of health care professionals or for treating health care consumers are innovating, researching, and piloting reforms.

Curricular programs developed to educate practicing health care professionals in end-of-life care have been developed for physicians, nurses, social workers, and pharmacists. For example, the American Medical Association's Institute for Ethics launched a program designed to educate practicing physicians in the core competencies of end-of-life care in 1999. Called Education for Physicians on End-of-Life Care (EPEC), this program has reached more than 300,000 health care professionals.<sup>8</sup> The reach of this curriculum has been further extended through the Community-State Partnerships network as most of its initiatives sponsor EPEC training in their states. The following sample of Community-State Partnership activities illustrates the way its coalitions help to disseminate this valuable training:

- The Kansas coalition offers a 2-day intensive EPEC training and stipends to interdisciplinary teams. In spring 2000, they had 11 physician/nurse teams; in 2001, they had 12 physi-

cian/nurse teams and trained an additional group of medical students from the University of Kansas. The coalition will offer EPEC by teleconference at several sites in fall 2001.

- In Iowa, EPEC modules are offered as an ongoing, bimonthly series with the Iowa Health System. The sessions attract on average between 35 and 40 attendees (residents and staff).
- The Kentucky coalition hosted four EPEC conferences between September 2000 and August 2001, which together attracted 144 participants, 25% of whom were physicians.

A curriculum for nurse educators, called the End-of-Life Nursing Education Consortium (ELNEC), has been developed by researchers at American Association of Colleges of Nursing and the City of Hope National Medical Center to improve the capacity of practicing nurses to care for the dying. During 2001, its first year, ELNEC will conduct five courses, all of which are over-subscribed. More than 400 nurse educators, representing all 50 states, have already been trained, and applications from undergraduates continue to outstrip current ELNEC capacity.

The Boston-based Institute for Healthcare Improvement is another important source of reform in this area. The Institute, in partnership with the Center to Improve Care of the Dying, combines best clinical practices and the best of medical and disease management to improve the dying experiences of patients and their families. Projects have focused on optimizing transfers among settings, advance care planning, pain management, and family support. Almost 100 organizations throughout the United States and Canada have participated in this initiative.<sup>9</sup>

Professional associations and regulatory bodies are also involved. Take for example, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) and its evolving attention to patients' rights. In 1988, the Commission required institutions to have a resuscitation policy; in 1992, standards were added that required institutions to have a mechanism for addressing ethical issues in patient care, for example, an ethics committee (which often deals with end-of-life questions); and in 2000, new standards for pain management were added. Other initiatives include the Federation of State Boards of Medical Examiners' guidelines for prescribing opioids, issued in 1999; and the American Society of Geriatrics position statement on care of dying pa-



tients, first issued in 1994 and revised in 1998. Dozens of similar organizations, many at the state level, have also established professional and institutional standards of practice.

At the community level, innovative demonstration projects are helping to integrate improved standards of care in communities and institutions. For example, in 1991 Oregon formed a multidisciplinary task force to address the problem of unwanted transfers and life-extending treatments. The group created the Physician Orders for Life-Sustaining Treatment (POLST) form and began a community-wide project to ensure that preferences for life-sustaining treatment accompany patients when they are transferred across multiple settings. In a study published in 1998, researchers found that POLST orders were universally respected. Study subjects received high levels of comfort care, and low rates of transfer for aggressive life-extending treatments.<sup>10</sup>

The Missoula Demonstration Project was established in 1996 with a 15-year vision for changing the social fabric of the community in regard to advanced illness, caregiving, death, and bereavement. The project used a series of community-based research projects to create a picture of end-of-life attitudes and experiences in Missoula County, Montana. The project is now focusing its efforts on bridging the gap (identified through research) between what people say they want at life's end and what they actually experience. Community outreach projects range from clinical interventions to improve pain management to involving school personnel, attorneys, and faith community members in a variety of advance care planning, end-of-life spiritual care, caregiving, and bereavement activities. The project makes extensive use of news media and the arts to stimulate conversations about end-of-life issues. Since the project's inception, thousands of individuals have participated in the project's research and more than 100 individuals have served on local task forces. Many thousands have participated in project-sponsored activities and events.

In 1999 Midwest Bioethics Center in Kansas City collaborated with area faith communities to develop and pilot a project called Compassion Sabbath. The project is an interfaith initiative that helps clergy and religious educators address the spiritual needs of dying people and their families. The project included educational and training programs for clergy and other faith leaders,

but the pinnacle of the project was Compassion Sabbath weekend, designated as the first weekend in February. During the first such weekend, February 5–6, 2000, an estimated 80,000 people and 900 faith leaders participated in Compassion Sabbath activities.

### *Public policy*

Public policymakers in many states have also embraced the issue of good end-of-life care. They are creating new policy, revising existing policy, and issuing interpretations of laws and regulations that are consumer friendly. For example:

- California Assemblywoman Helen Thomson, a founding member of Yolo Hospice in her district, engineered two state laws designed to improve the end-of-life care received by Californians. The first mandates the inclusion of pain management and end-of-life care in all California medical school curricula by June 2001. The second requires all health facilities (hospitals and nursing homes) to assess pain as a fifth vital sign.
- In 2000, West Virginia's legislature passed a Health Care Decisions Act that consolidated several pieces of advance care planning legislation and removed barriers, making the process more consumer friendly.
- In Rhode Island, legislation was passed in 1998 that instituted the Health Quality Performance Measurement and Reporting Program. The law requires the state department of health to assess and report publicly the quality of care in its acute-care facilities and nursing homes. Rhode Island is thus the first state to mandate comprehensive statewide assessment and report of patient satisfaction, quality-of-care measures, and administrative data for all licensed health care facilities.
- A final example is legislation passed in Hawaii, which not only increased reimbursement for hospice patients, but also permits drivers in their state who have made advance directives to indicate that they have done so on the face of their driver's license. According to Kokua Mau's project coordinator, Joanna Crocker, the legislation created a "teachable moment" for reformers in Hawaii and provided a stimulus for both the public and professionals to talk about death and dying.

Moreover, national groups that represent public policymakers, such as the National Association of Attorneys General, have also begun to recognize end-of-life care as a central issue for the citizens of their states. In June 2001, for the second time in 4 years, a plenary session of the meeting of the National Association of Attorneys General included a presentation on end-of-life issues. The attorneys general or their designees from more than 30 states heard updates about persistent legal and policy barriers as well as coalition efforts throughout the country to overcome them. Oklahoma Attorney General Drew Edmondson, who will become president of the association in 2002, emphasized to his colleagues the importance of the topic for attorneys general and his intention to make public engagement on end-of-life issues a top priority during his tenure. Edmondson plans to initiate a series of "listening" conferences in which attorneys general from around the United States will have opportunities to hear from constituents and policymakers. As Maryland Attorney General Joe Curran, who also addressed his colleagues at the June meeting, observed, "We need a policy environment in which quality end-of-life care thrives. Attorneys General can and should be full partners in efforts to reach that goal" (personal conversation, August 7, 2001).

### TIME FOR "PHASE TWO"

This is not the first time in America's history that the public has become intrigued with the topic of death. Three decades ago Elizabeth Kubler-Ross's research and teachings set in motion a number of reform activities that in some ways parallel those we have described. Compare the attention Kubler-Ross's 1969 book *On Death and Dying* received to that received by the SUPPORT Study published in 1995 in the *Journal of the American Medical Association*. Both studies cast care of the seriously ill and dying in an alarming and unacceptable light, and both attracted swift and significant attention. One could also compare Brian Clark's play *Whose Life Is It Anyway?* to *Wit*. Clark told the story of a young sculptor who is dreadfully injured in an automobile accident and wants to refuse life-sustaining treatment. The play raised important questions about the right

of competent patients to refuse treatment. It appeared on television (BBC) in 1972 and then on Broadway in 1978, and, like *Wit*, became a huge success. Then there was *Final Wish*, a book by journalist Betty Rollins, detailing the death of her mother and her mother's plea for assistance with dying, which can, in some respects, be compared to journalist Marilyn Webb's, *A Good Death*.

Still other parallels exist. For example, during the 1970s many universities and colleges initiated courses in "death and dying"; faith communities across the country offered similar adult education programs; and continuing pastoral care education programs embraced "dying with dignity." Beginning in the mid-1970s, several state legislatures passed "living will" legislation. Perhaps of most significance, and also in the mid-1970s, the modern hospice movement started by Dame Cecily Saunders at St. Christopher's Hospice in London found its way to the United States.

There are, of course, significant differences between the reform efforts that began in the 1970s and the current palliative care movement. Then, the issue of good end-of-life care was championed by a charismatic leader who took on almost cult status; individuals were transformed by reading Kubler-Ross's work and attending her lectures. Public engagement and education were focused primarily on assisted suicide.<sup>11</sup> Now, end-of-life issues are championed by many national leaders who come from different disciplines and experiences and by many more leaders working at the state, community, and institutional level. End-of-life care reform has transcended the level of the individual and found its way into the power structures of the health professions and public policy arena.

Still, we need to resist thinking that this public health crisis has been abated. It is far too early to declare success, or as Bill Moyers said at a Capitol Hill reception on September 6, 2001, before the initial airing of *On Our Own Terms*, "We have miles to go before we camp." We are optimistic about the degree and significance of the reforms underway—that leaders, best practices, and systemic approaches are emerging and the public and media are tuning in are great signs. But they are not signs of success. Rather, they indicate the completion of "phase one" and light the way to "phase two."

We have come to think that phase two needs to focus on "-izing" the movement, that is, on in-

stitutionalizing, systematizing, routinizing, and normalizing the best and most effective of these many activities, practices, and models. Many public policies remain impediments to the delivery and reimbursement of good end-of-life care; health care students still emerge from their professional schools without having seen a dying patient; and most of us still resist sharing our last wishes with those who will most likely have to act on them.

It should come as no surprise that end-of-life care reform is difficult work. We need to remember that end-of-life care, which we utter with ease and abbreviate to an innocuous acronym (EOLC), refers to nothing less than our shared and ultimate fate: death. The fact of human finitude has occupied the careers of theologians, philosophers, writers, artists, and scientists; it has given rise to voluminous literature, musical masterpieces, haunting poetry, and stunning scientific creativity. To face our dying and death or that of another is nothing less than an act of faith. We have to open ourselves to contingency, the unknown, and the unknowable. The challenge for reformers is to clear the path of obstacles so we can focus on the profundity of dying. As Pam Dobies, widow of Dr. William G. Bartholome, has said of his experience, "[T]here was a spiritual journey. And it was a hard one. But it happened and it happened because a clearing was made for that journey, a clearing void of distractions: distractions dealing with medical insurance problems; distractions of negotiating the medical maze; distractions of managing pain; distractions of administering to grieving family and friends. [Bill] was finally free to listen to his heart to resolve his life-long spiritual struggle."<sup>4</sup>

Anyone who knew Bill Bartholome or saw him in *On Our Own Terms* recognized that he was no "ordinary" dying patient, nor was his wife, Pam Dobies, the usual caregiver. They were people with knowledge, influence, and resources. They were also very private people. However, Bill and Pam allowed their story to become a matter for public viewing by millions of people because they

both recognized the public's role in reforming the care of seriously ill and dying persons and their families. They allowed more than 20 million television viewers into the most intimate event in their married lives.

To effect the social corrective that end-of-life reformers desire, many changes are needed. But change will happen if and only if the American public demands it. Demographics are our ally here. So called baby boomers are now struggling with the dying and death of their parents and have glimpsed in that struggle their own possible futures. We are confident that this age cohort—people accustomed to having a sense of control over their lives—will demand the same over their deaths. We only hope that this engaged public will remember to speak on behalf of those who often do not or cannot speak on their own behalf. The goods of this movement should not be reserved for only the lucky among us.

## ACKNOWLEDGMENTS

We thank the many people we mentioned in this article for sharing their stories with us and giving us permission to share them in turn. We would also like to thank our program coordinator, Amy Beaulieu, for her able research assistance, and Rachel Reeder for her fine editorial assistance.

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## Role of Ethics Committees, Ethics Networks, and Ethics Centers in Improving End-of-Life Care

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### ABSTRACT

This article chronicles the work of Midwest Bioethics Center, several community-state partnerships, and other local and national initiatives to determine their proper role and appropriate contribution. Professional education and development, institutional reform, and community engagement are areas of concern because ethics committees, networks, and centers sponsor workshops and conferences on palliative care for healthcare professionals, hold public forums, develop advance care planning projects, and provide expertise to legislators and other policymakers. The leading edge of the work being done by ethics committees, networks, and centers appears to be using continuous quality improvement methods, specifically the development of quality indicators, to promote accountability in end-of-life care reform efforts. This work is something that ethics committees can and should take on.

*Key Words.* Ethics Committees, Networks, and Centers; Quality Indicators; Community Engagement; Palliative Care Education; Continuous Quality Improvement

"One of the values of (ethics) committees is to tell healthcare providers what's happening in society and to educate them on major developments as they occur."

—Ronald E. Cranford

End-of-life issues have always been at the heart of the bioethics movement and have been the catalyst for most ethics committee consultations. Without exception, the early landmark cases that led to the creation of ethics committees were concerned with the proper care and appropriate treatment of seriously ill and dying patients, for example, Quinlan, Conroy, Sakeowitz, Brophy, Jobes, and others. Educational efforts by ethics committees often focus on patients' rights, advance directives, do-not-resuscitate orders, religious and theological views on medical treatment, end-of-life legislation, and landmark legal cases. Policy work of committees has attempted to provide guidance about these same issues. Therefore, it is unquestionably legitimate for ethics committees to be directly involved in the current palliative care movement. The question is "What is their proper role and appropriate contribution?"

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In their report, "Approaching Death: Improving Care at the End of Life," members of the Institute of Medicine's Committee on Care at the End of Life [1] stated that in their experience "many hospitals and nursing homes have no personnel with clearly designated palliative care expertise." They went on to say, "Hospital ethics committees may help resolve conflicts among patients, families, and clinicians about care goals for gravely ill patients, but this is not equivalent to expertise in symptom prevention and relief or in other aspects of palliative care" [1]. My experience as president and CEO of Midwest Bioethics Center (MBC) and Director of Community-State Partnerships to Improve End-of-life Care, a national program office established by the Robert Wood Johnson Foundation to improve end-of-life care through broad-based policy change at the state level, leads me to conclude that ethics committees, ethics committee networks, and ethics centers can and are doing more to advance good palliative care than simply helping to resolve conflicts.

Here I provide information about end-of-life activities by each of these entities from across the country. First, I wish to show how all three have been involved in my own community through a Kansas City project called Pathways to Improve End-of-Life Care: A Community Approach.



### Pathways to Improve End-of-Life Care: A Community Approach

In 1994, MBC staff attended a presentation by Dr. Joanne Lynn at what has been called the "mega-bioethics meeting"—a joint meeting of the Society for Health and Human Values, the Society for Bioethics Consultation, and the American Association of Bioethics—about preliminary data from the SUPPORT Study [2]. The picture the data painted of death in this country was grim: People often die alone, isolated in intensive care units for long periods, in pain, and with little regard for their advance directives. We were not surprised, but we were alarmed.

Based on this information, MBC initiated a dialogue in the Kansas City metropolitan area with healthcare professionals and consumers to explore the status of the dying and what we could do collaboratively to improve the care of seriously ill and dying members in our community. This discussion ultimately led to the comprehensive community-wide initiative called Pathways to Improve End-of-Life Care: A Community Approach.

This project had three focal points—professional education and development, institutional reform, and community engagement—13 strategies, and dozens of projects. It involved hundreds of volunteers and organizations. The thought leaders who originally partnered with MBC staff to design this initiative were members of MBC's Hospital Ethics Committee Consortium.

Established in 1986, the Ethics Committee Consortium had significant experience with policy issues related to end-of-life care. Over the years its members had developed policy guidelines about

- Patients' rights;
- Withholding/withdrawing treatment;
- Treatment of persons with HIV disease;
- Do-not-resuscitate orders for operating room and invasive procedure patients;
- The Patient Self-Determination Act;
- Advance care planning;
- Determining decisional incapacity.

In addition, most members are clinicians and many have significant experience in the care of seriously ill and dying patients.

The consortium structured its work to include five areas of concern and established a specific goal for each area.

- *Advance care planning*—to increase and improve dialogue with patients and their families about

end-of-life care and increase the use of advance directives in decision making for persons without decisional capacity.

- *Resuscitation status*—to increase the timely incorporation of informed resuscitation preferences into care plans of seriously ill and dying patients.
- *Psychosocial care*—to increase the availability of psychological, social, and spiritual support for seriously ill and dying patients.
- *Pain and symptom management*—to reduce the physical symptoms and emotional burdens of seriously ill and dying patients through improved palliative care.
- *Treatment reorientation*—to increase the timely and appropriate use of treatment redirection guidelines, including transfer to hospice.

Five corresponding subcommittees were formed with consortium members chairing each subcommittee. Consortium members, other volunteers chosen by consortium members, and MBC staff acquainted themselves with the recent literature in each area, identified common institutional barriers, and identified various strategies that could be initiated to foster improvement. Committees met every other week. More than 100 volunteers participated. Recommendations from each committee were circulated to the entire consortium for their review. During regular consortium meetings, all members were invited to contribute additional information. In June 1997, MBC published a resource manual and distributed it to every ethics committee chair in the Kansas City area [3]. Subsequently, copies were also distributed nationally.

The purpose of this article is not to present the Pathways project in its entirety; however, it is important to note that 11 local hospitals agreed to develop committees that would study the resource manual and develop projects to improve palliative care. All 11 hospitals agreed to work in all five areas. In some instances, the hospital's ethics committee actually took on this task, but in all instances, the ethics committee was closely involved.

When the Pathways project concluded in December 1999, 9 of the 11 participating hospitals had formed or were developing palliative care consultation services.

### Ethics Committee Opportunities to Improve End-of-Life Care

It is not only in Kansas City that ethics committees have been directly involved in efforts to improve

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palliative care within their institutions. At almost the same time that the Pathways project was going on in Kansas City, the Bioethics Committee at Montefiore Medical Center in New York was taking similar leadership. In an article titled "Palliative Care: A Bioethical Definition, Principles, and Clinical Guidelines," Linda Farber Post and Nancy Neveloff Dubler reported the following:

At Montefiore Medical Center, the Bioethics Committee and the Bioethics Consultation Service are repeatedly confronted with both theoretical and clinical issues related to end-of-life care. Inevitably, discussion would founder on the questions, "But what exactly is palliative care?" "When do you shift from aggressive treatment to palliation?" In response, a Palliative Care Subcommittee drafted a definition of palliative care, general profiles of patient groups for whom this type of care would be appropriate, and a set of principles and guidelines, some general and some specific to frequently encountered clinical situations [4].

To promote "wider and deeper discussion," Montefiore's Bioethics Committee members published a draft of their guidelines in 1997. These guidelines include a statement of philosophy and general guidance about assessment, communication, skills and knowledge, and education. The guidelines specifically address pain management, withdrawal of ventilatory support, withdrawal of dialysis, and withdrawal of nutrition and hydration.

That same year, internationally known nurse/researcher and pain expert, Betty R. Ferrell, argued that "while physicians, nurses, and other clinicians are most intimately involved with the management of pain, ethics committees can also play a vital role as agents of change, advocacy, and accountability" in the emerging problem of unrelieved pain [5]. She continued, "In concert with the need for improved clinical care for those individuals in pain, there is an unrecognized opportunity for ethics committees to provide the leadership that can result in institutional change, guaranteeing an improved standard of care for all patients in pain." In a table accompanying the same article, Ferrell made specific suggestions for how ethics committees can be involved:

- Increase visibility of the problem of unrelieved pain.
- Quantify the current status of pain management.
- Promote the need for, and acceptance of, an acceptable standard of care.
- Model the concept of an interdisciplinary approach to the problem of pain.
- Advance professional knowledge, beliefs, and competence in pain management.

- Ensure patient education regarding pain to enhance autonomy and to promote consumer expectations for pain relief.
- Lead institutional efforts to recognize and eliminate regulatory barriers to pain relief.
- Advocate for elimination of unethical practices related to patients in pain.
- Serve as a moral voice for vulnerable populations.
- Hold institutions accountable for the level of pain relief and recognize failure to relieve pain as a moral outrage.

#### **Ethics Networks Take on Pain Management Initiatives**

Through the Community-State Partnerships to Improve End-of-Life Care program, we have become aware of how other ethics committees, ethics networks, and ethics centers across the country are leading the movement to improve care of seriously ill and dying patients. Ethics networks are involved in a variety of such initiatives.

North Carolina may hold the record number of bioethics networks; it has five regional consortia:

- Bioethics Center of the Brody School of Medicine, Greenville, North Carolina;
- Bioethics Resource Group, Charlotte, North Carolina;
- Coastal Bioethics Network, Wilmington, North Carolina;
- Western North Carolina Network of Bioethics Committees, Asheville, North Carolina;
- Piedmont Bioethics Network in the Triad Region of North Carolina.

All have been actively involved in a Community-State Partnership grant led by the Carolinas Center for Hospice and End-of-life Care. They have provided workshops and conferences on palliative care for healthcare professionals, held public forums, developed advance care planning projects, and provided expertise to legislators and other policymakers. David Blackmon, PhD, bioethicist at Mission/St. Joseph Health System in Asheville, North Carolina, has said that the reason he pulled together a network of clinical ethics committees and groups was to provide "strength in numbers." The result in North Carolina is remarkable. To date there are 28 local end-of-life care coalitions working around the state (Hospice for the Carolinas, personal communication, August 2000).

Many believe that the work North Carolina networks and others are doing to engage "citizen/patients" is essential to the end-of-life movement. They believe that consumer demand for better care at the end-of-life is essential to reform. Many ethics networks, committees, and centers are now actively engaged in public education and outreach activities to inform consumers about what good palliative care is and how to advocate for it. Community-State Partnerships to Improve End-of-Life Care has published a resource manual entitled, "Making Our Voices Heard," to help those who are new to this work do it more effectively.

Oklahoma also has flourishing ethics networks in some cities. The Community-State Partnership grantee in Oklahoma is the Oklahoma Association of Healthcare Ethics, Inc., a fairly new freestanding ethics center. In response to an inquiry about how ethics networks and committees have been directly involved in their work, principal investigator Laura Cross, RN, JD, responded, "There is a network or roundtable of ethics committee chairs in both Oklahoma City and Tulsa that meet regularly. They have several times been a sounding board for our activities and have helped us think about priorities and next steps. They have also helped disseminate information and keep people involved" (personal communication, August 30, 2000).

Jim Keresztury, LCSW, ACSW, MBA, Project Manager of the West Virginia Initiative to Improve End-of-life Care, responded to the same inquiry:

Ethics networks are in a perfect position to lead the way in the reformation of our healthcare system to ensure quality end-of-life care for all Americans. For years ethics centers have cultivated caring networks of healthcare professionals who seek appropriate, qualitative, and patient-driven solutions to many of the difficult health decisions that patients and families face daily. These well-established networks consist mainly of players who are interested in quality end-of-life care—hospice, home health, community and regional hospitals, cancer centers, and nursing homes—as well as others. Working together these entities are making great strides in guiding healthcare in the United States to recognize the ethical significance of good, cost-effective end-of-life care (personal communication, August 30, 2000).

In addition to the network examples listed in the previous section, well-trained regional and municipal long-term care ethics committee networks are at work trying to infuse ethical perspectives into facility decision making, improve communication with families, and advance the cause of good palliative care.

- In 1998, the Kansas City Regional Long-Term Care Ethics Consortium developed a comprehensive set of palliative care policy guidelines. The guidelines promote palliative care as "the

primary goal of institutional long-term care" and provide a program of work to help institutions change practices.

- In California, the Long-Term Care Bioethics Consortium of the East Bay has worked with Oakland-area hospitals and nursing homes to promote use of an advance care planning tool called the Preferred Intensity of Treatment (PIT) form. The form was developed by the California Medical Association but with significant input from consortium members. The East Bay Consortium has also worked successfully with other groups to persuade the local Office of the Public Guardian to change its no-do-not-resuscitate/no-palliative care policy [6].

Despite these promising examples, a significant barrier to providing good palliative care in nursing homes is the tension that often exists between facility administrators and state surveyors. These relationships, which can be quite adversarial, may shift the focus of administrators' and healthcare providers' concern from providing good care to seriously ill and dying residents to protecting the interests of the institution. Ethics networks are also working on this issue.

In collaboration with Cooper Hospital University Medical Center, the New Jersey Office of the Ombudsman is developing 12 regional long-term care ethics committees as part of the New Jersey Stein Ethics Education and Development project (NJ SEED). Linda O'Brien, RN, MA, who represents Cooper Hospital University Medical Center on the project, says the 5.5-day training session that committee members must undergo empowers them with confidence to do the right thing. Although it is less than 3 years old, the NJ SEED project holds great potential for helping nursing homes provide better end-of-life care [7]. We hope that more regional and community long-term care consortia like the ones in Kansas City, the East Bay Area, and New Jersey will emerge.

#### Ethics Centers Are Leaders in End-of-Life Care

Bioethics centers, like ethics committees and networks, are also playing an important part in the movement to improve care of the seriously ill and dying. For example, Dr. Ira Byock's national program, *Promoting Excellence in Palliative Care*, which is also funded by the Robert Wood Johnson Foundation, is housed at the Center for Practical Ethics at the University of Montana in Missoula, and under Dr. Susan Tolle's direction, the Center for Ethics in Health Care in Oregon has been very involved in end-of-life reform efforts.



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Individuals working in both university and free-standing ethics centers are leading or are otherwise involved in several Community-State Partnership projects across the country:

- The Hastings Center has been involved in a project in New York and has an international reputation for its research and work in a variety of areas, including end-of-life care.
- In Utah, Dr. Jay Jacobson who directs the Division of Medical Ethics at the University of Utah School of Medicine notes that the overlap between subscribers to its monthly newsletter and "partners" in the Utah Community-State Partnerships project is "striking" (personal communication, August 2000).
- The St. Francis International Center for Health Care Ethics has been a partner in the Hawaii project. St. Francis Center staff members are active in medical school curriculum reform, continuing palliative care education for doctors and nurses, and implementing a "Pain as the Fifth Vital Sign" program in island nursing homes.
- In Nevada, an ethics and health policy center was formed to lead statewide end-of-life care reform. Dr. Barbara Thornton says they have "used ethics as an umbrella for end-of-life concerns." She says, "we are connected constantly with the ethics community and ethics committees." (personal communication, August 2000). Ethics committee members serve on all committees of the Nevada center. Linda Norlander, RN, MS, Partnership Director, reports, "We are fortunate to have two very active ethics organizations working with us" (personal communication, August 2000).
- In Minnesota, the Community-State Partnership grantee, a partnership among their three health plans, receives consultation services from the Minnesota Center for Health Care Ethics and the University of Minnesota Center for Bioethics.

The leading edge of the work being done by these ethics committees, networks, and centers appears to be the result of using continuous quality improvement methods to promote accountability in end-of-life care reform efforts.

#### Continuous Quality Improvement Efforts

An excellent resource manual on pain management has been published by the Wisconsin Cancer Pain Initiative. It is surprising, however, that this manual, "Building an Institutional Commitment to

Pain Management: The Wisconsin Resource Manual for Improvement" makes no mention of ethics committees. Still, the manual does encourage collaboration and recommends 12 different committees or groups within a hospital from which advocates for improved pain management should "enlist support." Although the hospital ethics committee is not included in the list, in the "Where to Begin" section, the authors Debra Gordon, June Dahl, and Karen Kunz Stevenson encourage a systemwide strategy and recommend a continuous quality improvement (CQI) approach as an "excellent framework for institutionalizing pain management" [8]. Many leaders in the end-of-life care movement are beginning to make this same recommendation.

In a special supplement to the *Journal of the American Geriatrics Society: Findings from SUPPORT and HELP*, Joanne Lynn and others involved in the SUPPORT Study published an article titled, "Rethinking Fundamental Assumptions: SUPPORT's Implications for Future Reform"[9]. The authors argue that "rather than assuming, as SUPPORT did, that utility maximization for each patient can be accomplished by close adherence to a decision analytic model at the individual level, reformers might do better to adopt a model of continuous quality improvement at the systems level."

In their summary (p. S220), the authors write

[We now question the fundamental assumption [of SUPPORT]: that the course of care for the seriously ill hospitalized patient is the result of individual, patient-level decision-making that could be improved with better counseling and information. Instead, the course of care may well be shaped largely by how the care system is organized and by the interpersonal meanings, ascribed to various cues and signals that shapes the predictable patterns of care. . . . Future interventions may be more effective if they address system change and quality improvement.

We agree. However, it appears that the authors are unaware of the involvement of what they refer to as "medical ethics" at the policy level and efforts of ethics committees to use a CQI methodology to make systemic improvements in end-of-life care. Consider, for example, the following possibility: Inspired by the efforts of one of its member organizations, Trinity Lutheran Hospital in Kansas City, Missouri, members of MBC's Ethics Committee Consortium, have recently decided to develop a guidelines document for using "ethics quality indicators."

These indicators will be broader than quality indicators about end-of-life care, but like the bioethics committee movement itself, it is impossible that they will not include indicators about care of seriously ill and dying patients. Trinity Lutheran's medical staff recently approved four "Performance

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Improvement Indicators" at the recommendation of the hospital's Ethics Committee [10]. They chose the following indicators:

1. The patient's record contains physician documentation of the rationale for the patient's code status.
2. If the patient resuscitation category was changed during the patient's hospital stay, there is physician documentation by the physician about the reason for the change and patient/surrogate agreement.
3. If the patient has an advance directive, the wishes of the patient were followed.
4. For patients placed on life support, the record reflects
  - a. That a meaningful discussion took place with the patient/surrogate;
  - b. That the treatment decision supports the patient's known values and goals of life.

(Life support categories include placement of feeding tubes, initiation of dialysis, and ventilator support for more than 7 days.)

In routine reviews by the Performance Improvement Quality Committee, patients' charts will be scrutinized for these indicators. If the audits indicate that a physician is not meeting these standards, that information will be sent to the Peer Review Committee and the usual measures will be taken. Given the data on the success of the peer review in other clinical areas, we believe that this initiative is a promising effort.

Although each of these indicators has a significant role in ensuring that good end-of-life care is provided, they are not sufficient to improve palliative care overall. Over the next few months, members of the ethics committee consortium will recommend other possible indicators, including, no doubt, the assessment and treatment of pain. Other indicators to be considered in the guidelines include hospice referrals for patients who die during hospitalization, involvement of chaplaincy, bereavement services for families, and patient/family satisfaction.

Concerns expressed thus far by members of the Kansas City Ethics Committee Consortium about a performance improvement approach are not unusual in kind. Can they get buy-in from their medical staff? How will such indicators be measured? And do other hospitals have the resources necessary to implement a program like Trinity Lutherans? We will look to others working in this area who are further along for guidance. For example, Joan Teno, Associate Professor of Community Health

and Medicine at Brown University's Center for Gerontology and Health Care Research and principal investigator for a Community-State Partnership project in Rhode Island, and other noted end-of-life care reformers have suggested that quality indicators are developed specifically for dying nursing home residents and that we expand quality improvement efforts to include advance care planning, spirituality, and patient satisfaction. In collaboration with the Rhode Island Department of Health and Aging 2000, a nonprofit consumer education organization, Teno is leading an innovative project to help Rhode Island nursing homes with internal quality improvement in end-of-life care. The coalition plans to develop and test three to four new indicators on pain management and advance care planning for dying residents.

Others are pressing the envelope even further and urging the use of quality indicators as an accountability instrument. Susan Tolle, MD, at the Oregon Center for Ethics in Health Care, has recommended that medical boards define quality indicators for the undertreatment of pain, and recently the Oregon Medical Board disciplined a physician for failing to give six seriously ill or dying patients adequate pain medication. Tolle says, "At the moment, physicians in other states can get into trouble only by writing prescriptions. But refusing to write any also falls into the scope of bad practice"[11].

Measuring the effectiveness of efforts to improve end-of-life care is important work, although this kind of research is new for many ethics committees, networks, and centers, and how the indicators can best be used may be controversial in some instances.

### Conclusion

In their report on a United Hospital Fund of New York project to improve end-of-life care in 12 New York hospitals, Connie Zuckerman and Anne MacKinnon wrote

Before hospitals can achieve the real goals of having the right set of services and establishing some means of coordinating their deployment in a timely and effective way, they must answer some fundamental questions related to authority and accountability. "Is palliative care a component of good primary care, or is it a realm for expert intervention?" "Should both acute care and palliative care be the goal in an individual hospital?" "Who has the authority to initiate and deliver palliative care?" "Who takes the lead in an integrated plan of care?" And "how, if at all, can hospitals encourage teamwork among physicians, whose profession has traditionally cultivated autonomy?"[12]

Our experience leads us to conclude that ethics committees have the authority and the responsibility

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ity to "initiate" palliative care. Furthermore, we believe ethics committees, ethics networks, and ethics centers have an important role to play in the development of social policy and community engagement. In some instances, those involved in ethics will have to take on new work and learn new methodologies, such as continuous quality improvement. However, our experience and early results lead us to conclude that this role is one that ethics committees can and should take on.

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